

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the foregoing amendments and the following remarks.

Oath/Declaration:

After discussing this issue with Examiner Marjorie Christian, the Examiner agreed to withdraw this issue in a later office action or notice of allowance as the original Oath/Declaration filed in the currently pending application was found to in fact not be defective.

Information Disclosure Statement:

The Examiner claims that the information disclosure statement filed on August 1, 2006 fails to comply with 37 CFR 1.98(a)(3). A concise explanation of the relevance of foreign patents DE 4230077 (US 5,879,554) and EP 0168783 (US 4,906,375) is included with this response to be place in the application file, as requested by the Examiner.

US 5,879,554: Relates to a synthetic membrane consisting of a mixture of polysulfone and sulfonated polysulfone and no

more than 20 wt. % of other polymers as well as a method for manufacturing this synthetic membrane.

US 4,906,375: Relates to asymmetrical microporous fibers, particularly for the treatment of blood, and made up of a first polymer which is hydrophobic and a second polymer which is hydrophilic as well as a process for the manufacture of such fibers.

Claim Status

Claim 12 was amended and claim 13 was cancelled. Claims 1-12 and 14-16 are pending. No new matter was added.

§102 Claim Rejections

Claims 1-9, 12, and 15-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by WO 2000/050160 (hereinafter Hou). Applicant traverses.

To anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ

344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may only rely on PCT Article 33(3). See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

Hou does not disclose a method for production of an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer as is described in the instant invention. **Instead, Hou discloses a negatively charged microporous membrane comprised of a porous substrate and a crosslinked coating (Hou, page 1, lines 10-13) and a process for preparing these membranes. (Hou, page 11, line 16 - page 12, line 4).**

In contrast, the instant invention describes a process for the production of a membrane. During process step c), i.e. before a membrane and a membrane structure have been formed, the shaped polymer solution is brought into contact with a precipitant system which contains a polyelectrolyte with a negative fixed charge. (Specification, page 5, lines 10-21).

As a result of the contact of the shaped polymer solution with the precipitant system, the membrane structure develops and the membrane is formed. It is assumed that during coagulation the polyelectrolyte with a negative fixed charge is anchored in the emerging separating layer of the membrane of the instant invention by interlocking and entanglement between the polymer chains of the polyelectrolyte and those of the membrane forming polymer. (Specification, page 14, lines 20-30).

Hou discloses an unrelated and completely different process wherein a porous substrate is used. (Hou, page 9, lines 12-13). The porous substrate can be prepared by a phase inversion process which may result in a phase inverted membrane. (Hou, page 9, line 29 - page 10, line 3). **The porous substrate described in Hou is a pre-fabricated substrate which is coated with a coating solution AFTER fabrication.** (Hou, page 10, lines 4-18). The coating solution may contain an anionic acrylic monomer. (Hou, page 8, lines 8-9). Hou describes that the porous substrate can be coated by immersion in a coating solution for a given period of time to insure complete or substantially complete coating of the pore walls. (Hou, page 10, lines 4-10). **The use of a prefabricated porous substrate which is coated with a coating solution in a SEPARATE PROCESS STEP is contradictory to the instant invention.** Therefore, the

method described in Hou does not fulfill the criteria of method of claim 1 of the instant application.

Thus, Hou discloses the application of a solution containing an anionic acrylic monomer onto a pre-fabricated membrane through a coating process, while the instant invention discloses bringing a shaped polymer solution into contact with a precipitant system which contains a polyelectrolyte with a negative fixed charge which results in the development of the membrane structure and the formation of the membrane.

As stated above, Hou does not disclose a method for production of an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer as disclosed in claim 1. Accordingly, Hou does not disclose all of the elements of claim 1, and hence, does not anticipate claim 1. Therefore, this rejection must fail.

In reference to claims 2-9, "[I]f an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. *Kovin Assoc. v. Extech/Exterior Technologies*, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292,

1296 (Fed. Cir. 2002). Thus, claims 2-9 are not unpatentable over Hou and should be allowed.

Claim 12 stands rejected under 35 U.S.C. §102(b) as being anticipated by WO 2000/050160 (hereinafter Hou). Applicant traverses.

Again, to anticipate a claim under 35 U.S.C. §102(b), a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 USPQ 1264, 1271 (Fed. Cir. 1984). Where a reference discloses less than all of the claimed elements, an Examiner may only rely on PCT Article 33(3). See *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985).

The above comments regarding Hou are incorporated herein. Claim 12 has been amended to include the language from claim 13

in order to further clarify claim 12 in comparison to the prior art. Hou does not disclose an integrally asymmetric membrane with at least one separating layer and a supporting layer, characterised in that a polyelectrolyte with negative fixed charges is physically bound in the separating layer and characterised in that the supporting layer is free from polyelectrolyte as disclosed in claim 12.

In rejecting claim 13 of the instant invention the Examiner alleges that Hou discloses that the porous substrate is coated in polyelectrolyte by known methods where it is implicit that the supporting layer is free from polyelectrolyte. (Office Action, page 6, lines 7-10). However, this could not be further from the truth. There is no disclosure within Hou which allows one of ordinary skill in the art to conclude that the coated, porous substrate which results from the process disclosed in Hou and relied upon by the Examiner possesses a separating layer which is free of polyelectrolyte. To the contrary, Hou explicitly discloses the use of a dip coating in which the substrate is immersed in the coating solution resulting in a complete or substantially complete coating of the pore walls. (Hou, page 10, lines 7-10). The resulting homogeneous coating described in Hou directly contradicts the integrally asymmetric membrane disclosed in the instant invention which has a

supporting layer, adjoining the separating layer, that is free from polyelectrolyte. (Specification, page 15, lines 7-9).

Additionally, Hou does not explicit disclose, or even hint, that the polyelectrolyte would be removed from the supporting layer during leaching. It is essential for the coated substrates of Hou that the coating is cured or crosslinked. "The resulting coated substrate is cured to effect the curing and crosslinking of the coated composition." (Hou, page 10, lines 16-18). It is known by those having skill in the relevant art that through crosslinking a material is made insoluble. This was apparently the goal in Hou because even after curing and crosslinking, the coated membranes disclosed in Hou can be washed. The Examiner's reliance on Hou is misplaced in this instance as the washing described in Hou ("The resulting membrane can be washed to leach out any extractable in the membrane." page 10, lines 28-29) does not mean that part of the coating is removed from the substrate, let alone that the coating is specifically removed from only one of the layers of a substrate. Instead, this language simply means that any unreacted materials are removed from the coated substrate in order to prevent their presence from causing any problems when the membrane is later in use. Again, this is common knowledge to those of ordinary skill in the art.

As stated above, Hou does not disclose an integrally asymmetric membrane with at least one separating layer and a supporting layer, characterised in that a polyelectrolyte with negative fixed charges is physically bound in the separating layer and characterised in that the supporting layer is free from polyelectrolyte as disclosed in claim 12. Accordingly, Hou does not disclose all of the elements of claim 12, and hence, does not anticipate claim 12. Therefore, this rejection must fail.

In reference to claims 15-16, "[I]f an independent claim is not anticipated by prior art, then its dependent claims, which necessarily include the limitations of the independent claim, are not anticipated either. *Kovin Assoc. v. Extech/Exterior Technologies*, 2006 U.S. Dist. LEXIS 63250 (N.D. Ill. 2006), citing *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002). Thus, claims 15-16 are not unpatentable over Hou and should be allowed.

§103 Claim Rejections

Claims 10-11 and 13-14 stand rejected under 35 U.S.C. §103(a) as being obvious over WO 2000/050160 (hereinafter Hou)

as evidenced by U.S. Patent No. 5,919,370 (hereinafter Rottger). Applicant traverses.

The above comments regarding Hou are incorporated herein. As stated above, Hou does not disclose a method for production of an integrally asymmetric membrane with at least one separating layer and a supporting layer adjoining the separating layer as disclosed in claim 1. Additionally, Hou also does not disclose an integrally asymmetric membrane with at least one separating layer and a supporting layer, characterised in that a polyelectrolyte with negative fixed charges is physically bound in the separating layer and characterised in that the supporting layer is free from polyelectrolyte as disclosed in claim 12.

The Examiner claims to have established a *prima facie* case of obviousness against the instant application. MPEP § 2143 "Basic Requirements of a *Prima Facie* Case of Obviousness" states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations.

Regarding the third criterion, the court has stated that "to establish *prima facie* obviousness of a claimed invention,

all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicant contends that none of the prior art references, neither Hou, nor Rottger, alone or in combination, teach, suggest, or provide a motivation for a method for production of an integrally asymmetric as disclosed in claim 1 or claims 10 and 11. Additionally, Applicant contends that none of the prior art references, neither Hou, nor Rottger, alone or in combination, teach, suggest, or provide a motivation for an integrally asymmetric membrane as disclosed in either claim 12 or claim 14.

The prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above,

it is clear that Hou and Rottger fail to teach or suggest all the limitations of Applicant's claims.

The Examiner's reliance on both Hou and Rottger is misplaced. As explained above, Hou discloses a method for producing a coated substrate wherein a pre-fabricated porous substrate is coated in a subsequent processing step which directly contradicts the method disclosed in the instant invention. Rottger discloses a process for the manufacturing of hollow fibers whereby an interior filler is used. However, Rottger is silent about the addition of a polyelectrolyte having a negative fixed charge for use as an interior filler. There is no disclosure within either Hou or Rottger which teaches, suggests, or provides a motivation to use a precipitation medium comprised of a polyelectrolyte having a negative fixed charge during the manufacturing of a membrane which would allow an individual who is skilled in the art to produce a membrane as disclosed in the instant invention.

Accordingly, Hou as further evidenced by Rottger does not disclose all of the elements of claims 10, 11, and 14. Therefore, this rejection must fail. Thus, claims 10, 11, and 14 are not anticipated by Hou and Rottger and should be allowed.

No new matter has been added.

Conclusion

In view of the foregoing, Applicant respectfully requests an early Notice of Allowance in this application.

Respectfully submitted,



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